

K013107

FEB 26 2002

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

**Applicant:** Karl Storz Endoscopy - America, Inc.  
600 Corporate Pointe Drive  
Culver City, CA 90230  
(310) 338-8100

**Contact:** James A. Lee, Ph.D.  
Regulatory Affairs Specialist

**Device Identification:** Common Name:  
Bioabsorbable Interference Screw

Trade Name: (optional)  
KSEA Bioabsorbable Interference Screw MegaFix™

**Indication:** The KSEA Bioabsorbable Interference Screw MegaFix™ is intended for use by qualified surgeons for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction.

**Device Description:** The KSEA Bioabsorbable Interference Screw MegaFix™ is biocompatible and biodegradable.

**Substantial Equivalence:** The KSEA Bioabsorbable Interference Screw MegaFix™ is substantially equivalent to the predicate devices since the basic features and intended use are similar. The minor differences between the KSEA Bioabsorbable Interference Screw and the predicate devices raise no new issues of safety and effectiveness, as these minor differences have no effect on the performance, function or intended use of the device.

Signed: \_\_\_\_\_

James A. Lee, Ph.D.  
Regulatory Affairs Specialist

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 26 2002

Karl Storz Endoscopy  
James A. Lee, Ph.D.  
Regulatory Affairs Specialist  
600 Corporate Pointe, 5<sup>th</sup> Floor  
Culver City, California 90230-7600

Re: K013107

Trade Name: KSEA Bioabsorbable Interference Screw Megafix™  
Regulation Number: 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: December 12, 2001  
Received: December 13, 2001

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

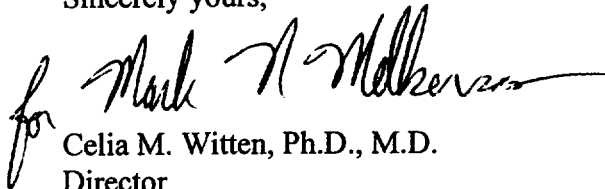
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark H. Melker

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K013107

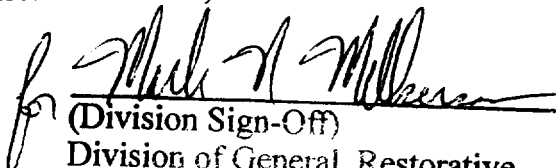
510(k) Number (if known): Not yet assigned

Device Name: KSEA Bioabsorbable Interference Screw MegaFix™

Indications for Use: The KSEA Bioabsorbable Interference Screw, MegaFix™ is intended for use by qualified surgeons for tibial and femoral fixation (primary anchorage) of tendon grafts in human cruciate ligament reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K013107

Prescription Use: yes OR Over-The-Counter Use: No  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)